EC Declaration of Conformity

Manufacturer:
DeVilbiss Healthcare LLC
100 DeVilbiss Drive
Somerset, PA 15501, USA

EC Authorized Representative:
DeVilbiss Healthcare GmbH
Kamenzerstraße 3, 68309
Mannheim, Germany

1. Suction Units (UMDNS 13-846):

Catalogue nos.: *7325D-AP, 7325D-D, 7325D-D-EXF, 7325D-I, 7325D-LA, 7325D-U, 7325P-AP, 7325P-D, 7325P-D-EXF, 7325P-I, 7325P-LA, 7325P-T, 7325P-U*

Classification (MDD Annex IX): *IIa (Rule 11)*

Conformity Assessment Procedure: *MDD 93/42/EEC, Annex II excluding Section 4*

2. Accessories:

Product Description (Catalogue no.):

6' (1.8m) Patient Tubing, PVC	*6305D-611*
DC Power Cord, 1 each	*7304D-619*
800 ml Disposable Container w/ internal filter cartridge, splash guard, 4 ⅜" tubing, 48 each	*7305D-632*
Collection Container Kit (internal filter cartridge, splash guard, 800 ml container, 4 ⅜" and 6" tubing package)	*7305D-633*
Filter Cartridge assy, 1 pk. (for 800 ml disposable container use)	*7305D-634*
Filter Cartridge, 12 pk. (for 800 ml disposable container use)	*7305D-635*
4.5" (11.4cm) Connection Tubing, silicon	*7305D-639*
Collection Container Kit (1200 ml reusable container, external bacteria filter, elbow, 4 ⅜" tubing)	*7314D-603*
1200 ml Reusable Container (external bacteria filter, elbow, 4 ⅜" tubing) 6 pk.	*7314D-604*
AC to DC Power Adapter/Charger	*7314P-613*
External Bacteria Filter (non-sterile), 12 pk. (for reusable container use)	*7305D-608*
Battery, replacement assy.	*7325P-614*
Carry Case	*7325D-635*
Power Cord, US	*DV51D-606*
Power Cord, EU	*DV51D-607*
Power Cord, UK	*DV51D-608*
Power Cord, AU	*DV51D-609*

Applied standards: All applicable harmonized standards as adopted under the EC Directive 93/42/EEC and published in the Official Journal of the European Communities. *(See attached listing)*

This Declaration of Conformity is based on the EC Directive 93/42/EEC, Annex II.3 and supported by the TÜV NORD CERT GmbH (0044) certificate, with reference to articles 1 and 3 of the directive 93/42/EEC.

Notified Body: *TÜV NORD CERT GmbH*
Langemarckstrasse 20, 45141 Essen, Germany

Identification No.: *0044*

EC Certificate No.: *44 232 117803*

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We, DeVilbiss Healthcare LLC., hereby declare under our sole responsibility that the above-mentioned products comply with the essential requirements and provisions of Council Directive 93/42/EEC.

Validity of this Declaration: *2019-08-07 – 2024-05-26*

Somerset, PA, JUN 14, 2022

Place, Date

Roberto L. M—

Roberto Munoz Director, Regulatory Affairs and Audit

Name and Position

Applied Standards:

7325 series
BS EN ISO 10079-1:2015 + AMD 1:2019 (Ed 3.0) - Medical Suction Equipment
IEC 60601–1:2005+A1:2012 (Ed 3.0) - Medical Electrical Equipment—Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems [FDA Recognized Consensus Standard]
IEC 60601-1-2:2014 (Ed 4.0), Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility – Requirements and tests (FDA Recognition Number 19-8)
IEC 60601-1-6:2010 + AMD 1:2013 (Ed. 3.1) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (associated with IEC 60601-1 Ed. 3.0) (FDA Recognition Number 5-89)
IEC 60601-1-9:2007 + A1:2013 (Ed. 1.1) Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design (associated with IEC 60601-1 Ed. 3.0)
IEC 60601-1-11:2010 (Ed 1.0), Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (FDA Recognition Number 19-14)
IEC 62366-1:2015 (Ed. 1.0) – Medical devices - Application of usability engineering to medical devices (FDA Recognition Number 5-114)
ISO 14971:2019 (Third Ed), Medical devices - Application of risk management to medical devices [FDA Recognized Consensus Standard Number 5-125]
ISTA Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or less (standard).